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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/046,840	03/24/1998	DAKAI LIU	ENZ-56(DIV3)	2602

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EXAMINER	
GUZO, DAVID	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/046,840	Applicant(s) LIU ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-95,97,99,101 and 103-110* is/are rejected.

7)☒ Claim(s) *96,98,100 and 102* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 3/24/98 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85-86, 92-94, 97,101 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al.

Applicants claim a first viral vector comprising retroviral sequences (i.e. LTR sequences), a retroviral packaging component(s), non-retroviral viral vector sequences, and a nucleic acid sequence coding for a exogenous gene or exogenous nucleic acid sequence wherein when introduced into a packaging cell (which provides one or more packaging components for the second vector), said first vector produces a second viral vector comprising said non-retroviral vector sequences, a promoter or terminator and the exogenous nucleic acid sequence(s). Applicants also claim a packaging cell (which can be derived from NIH 3T3 cells) comprising a receptor for the second vector and wherein the packaging components for the second vector are expressed transiently from non-integrated sequences.

It is noted that a retroviral packaging component can be a retroviral packaging signal sequence.

Miller et al. (BioTechniques, 1989, Vol. 7, No. 9, pp. 980-990, see whole article, particularly Figures 1-3, right column on p. 981, first two columns on p. 986) recites a first DNA vector (i.e. LNCX, LNSX, etc.) comprising retroviral sequences (i.e. LTRs), a

retroviral packaging component (packaging signal sequence), non-retroviral viral vector sequences (i.e. SV40 or CMV promoters) and a sequence encoding a exogenous gene (neo) wherein the first vector upon introduction into a packaging cell line produces a second vector (retroviral vector RNA sequence (comprising a promoter) to be packaged into infectious retroviral particles). Miller et al. also recites a packaging cell line (which can be NIH 3T3 cells) and packaging cell lines (PA317) comprising a receptor for the retroviral vector particles produced by said cell wherein the packaging components are expressed transiently from non-integrated sequences. Miller et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 85-94 and 103-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong-Staal et al.

Applicants claim a first vector comprising retroviral sequences, retroviral packaging component(s), non-retroviral viral vector sequences and nucleic acid sequences coding an exogenous gene or exogenous nucleic acid sequence wherein when introduced into a packaging cell (providing one or more packaging components

for the second vector), said vector produces a second viral vector comprising said non-retroviral viral vector sequences and said exogenous gene or nucleic acid sequence. Applicants also claim packaging cell lines wherein the packaging components for the second vector are derived from transient expression of non-integrated nucleic acid sequences.

Wong-Staal et al. (previously cited by the examiner, see whole document, particularly Figs. 11-13, Claims 1-14, columns 6-7, 12 and 16-18) recites a first vector (which can be a DNA plasmid vector) comprising retroviral sequences (such as LTRs), retroviral packaging components (i.e. gag or pol or env or a combination of two or more components, etc.), non-retroviral viral vector sequences (AAV sequences such as AAV ITR elements) and nucleic acids encoding a anti-viral protein or antisense nucleic acid wherein said vector produces a second vector (retroviral RNA vector) upon introduction of the first vector into a packaging cell which provides one or more packaging components (derived from transient expression of non-integrated nucleic acid sequences) for the second vector. Wong-Staal et al. also recite a cell line comprising retroviral sequences (such as LTR sequences), non-retroviral viral vector sequences such as the AAV ITRs, nucleic acid sequences coding for an exogenous gene or nucleic acid sequence and packaging components (provided in helper plasmids) for the AAV vector sequence. Wong-Staal et al. therefore teaches the claimed invention.

Claims 85-86, 92-94, 95, 97, 99, 101 and 103-105 and are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel.

Applicants claim a first vector comprising retroviral sequences (i.e. LTR sequences), retroviral packaging component(s), non-retroviral viral vector sequences, nucleic acid sequences coding for an exogenous gene or exogenous nucleic acid sequence, wherein when introduced into a packaging cell said first vector produces a second vector comprising said non-retroviral viral vector sequences and said exogenous nucleic acid sequences as well as one or more promoters, terminators, etc. Applicants also claim packaging cells (i.e. derived from NIH 3T3) comprising a receptor for the first vector and/or a receptor for the second vector and wherein the components for packaging are from transient expression of non-integrated nucleic acid sequences.

Curiel (U.S. Patent 6,333,030, issued 12/25/01, priority to 02/04/97, see claims 1-10, the paragraph bridging columns 4-5, Examples 3-4, 18 and 21) recites a first vector (adenoviral vector) comprising retroviral sequences (LTRs), retroviral packaging components (packaging signal sequence), non-retroviral viral vector sequences (adenoviral vector sequences), nucleic acid sequences coding for an exogenous gene or sequence wherein when vector is introduced into a packaging cell (transiently expressing non-integrated sequences encoding packaging components for the second vector) produces a second vector (retroviral vector) comprising the non-retroviral sequences and the exogenous gene or sequences. Curiel also recites packaging cells comprising retroviral sequences, non-retroviral viral vector sequences (adenoviral sequences), sequences encoding an exogenous gene and packaging components for said non-retroviral vector (adenoviral) sequences. Curiel therefore teaches the claimed invention.

Claims 85, 86, 92-94, 97 and 101-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Finer et al.

Applicants claim a first vector comprising retroviral sequences (i.e. LTR sequences), retroviral packaging component(s), non-retroviral viral vector sequences and nucleic acids coding for an exogenous gene or exogenous nucleic acid sequence, wherein when introduced into a packaging cell line said first vector produces a second viral vector comprising said non-retroviral vector sequences, said exogenous gene or nucleic acid sequence (encoding a protein or antisense), one or more promoters or terminators, etc. and wherein said cell provides one or more packaging components for said second viral vector. Applicants also claim packaging cells (which can be 293 cells or NIH 3T3 cells) comprising a receptor for the second vector and wherein the sequences encoding the packaging components for the second vector are stably integrated into the genome of the packaging cell.

Finer et al. (U.S. Patent 6,218,187, issued 04/17/01, priority to 08/21/95, see whole document, particularly column 3, lines 30-67; column 4, lines 40-49; column 5, lines 31-56; paragraph bridging columns 5 and 6; paragraph bridging columns 11-12; Example 1, etc.) recites a first vector (a DNA plasmid vector) comprising retroviral sequences (LTR sequences), retroviral packaging components (retroviral packaging signal sequence), non-retroviral viral vector sequences (SV40 or CMV sequences), and nucleic acid sequences encoding a gene or nucleic acid sequence of interest wherein when said first vector is introduced into a packaging cell (293 cell) having the sequences encoding the packaging components integrated into the cell genome, a

second vector (retroviral RNA vector) is packaged and generated. The 293 cells have a receptor for the second vector as they can be infected by said vectors. Finer et al. therefore teach the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 108-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 108-109 (and dependent claims) are vague in that there is no antecedent basis for the term "said second viral vector" in the claim from which these claims depend.

Claims 96, 98 and 100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
October 4, 203

DAVID GUZO
PRIMARY EXAMINER